§ 105.4 Termination of licenses and permits for inactivity.

(a) If a biological product has not been prepared by a licensee, or imported by a permittee for a period of five years or more, the Administrator may require the licensee to show intent to resume production, or the permittee to show intent to resume importation, within six months of notification. If the licensee does not resume preparation, or the permittee does not resume importation, within six months of notification, or within a mutually agreeable period, the product license, or permit, may be terminated by the Administrator.

(b) When a license or permit is terminated, the licensee or permittee shall continue to be subject to applicable records provisions of § 116.8.

10. In 9 CFR part 116, the heading for the part would be revised to read as follows:

PART 116—RECORDS AND REPORTS

11. The authority citation for part 116 would continue to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.17, 2.51, and 371.2(d).

12. In § 116.1, paragraphs (a), (b) and (c) would be redesignated as paragraphs (a)(1), (a)(2), and (a)(3), respectively; redesignated paragraph (a)(1) would be revised; the introductory paragraph would be designated as paragraph (a) and would be revised; and new paragraphs (b) and (c) would be added to read as follows:

§ 116.1 Applicability and general considerations.

(a) Each licensee, permittee, and foreign manufacturer of biological products imported into the United States shall maintain, at the licensed or foreign establishment in which the products are prepared, detailed records of information necessary to give a complete accounting of all the activities within such establishment. Such records shall include, but shall not be limited to, the items enumerated in this part.

(1) Records shall be made concurrently with the performance of successive steps in the development and preparation of biological products, including new products under development. Such records shall include the date and where critical, the time that each essential step was taken, the identity and quantity of ingredients added or removed at each step, and any gain or loss of product from the beginning to the end of product preparation.

* * * * *

(b) In the case of imported products, each permittee shall maintain at the permittee's place of business detailed and accurate records that are relevant to each imported product and that include, but are not limited to, importation documents, sampling records, tests summaries, shipping records, and inventory and disposition records as required in § 116.2.

(c) When authorized by the Administrator, the licensee, permittee, or foreign manufacturer may maintain and retain records required under part 116 at an alternative location. Such authorization shall be confirmed by the filing of an addendum to the plot plan legend. The addendum shall list the location of the records and the condition of their storage and shall permit the inspection of the records by APHIS inspectors, or foreign inspectors acting on behalf of APHIS.

(Approved by the Office of Management and Budget under control number 0579–0013)

§§ 116.2, 116.3, 116.4, and 116.6 [Amended]

13. At the end of §§ 116.2, 116.3, 116.4, and 116.6, the reference to OMB control number ''0579–0059'' would be removed and the number ''0579–0013'' would be added in its place.

14. Section 116.5 would be revised to read as follows:

§ 116.5 Reports.

(a) When required by the Administrator, reports containing accurate and complete information concerning biological products, including but not limited to, product development and preparation, consumer reports, and market suspensions and recalls, shall be prepared and submitted to the Animal and Plant Health Inspection Service by the licensee, permittee, or foreign manufacturer whose products are being imported or offered for importation. Unless otherwise authorized by the Administrator, records necessary to make such reports shall be maintained in each establishment.

(b) If, at any time, consumer reports concerning the use of products raise questions regarding purity, safety, potency, or efficacy of the products; or a biological product appears to be unsatisfactory or is found to have been prepared, tested, or distributed in violation of the Virus-Serum-Toxin Act or the regulations; the licensee, permittee, or foreign manufacturer shall immediately report the circumstances and the action taken, if any, to the Animal and Plant Health Inspection Service.

(Approved by the Office of Management and Budget under control number 0579–0013)

15. In § 116.7, the second sentence would be revised to read as follows:

§ 116.7 Test records.

* * * Summaries of such tests shall be prepared from such records and submitted to the Animal and Plant Health Inspection Service using APHIS Form 2008 or an acceptable equivalent form prior to release of the serial or subserial. * * *

* * * * *

16. Section 116.8 would be revised to read as follows:

§ 116.8 Completion and retention of records.

All records (other than disposition records) required by this part shall be completed by the licensee, permittee, or foreign manufacturer before any portion of a serial of any product may be marketed in the United States or exported. All records shall be retained at the licensed or foreign establishment or permittee's place of business for a period of two years after the expiration date of a product, or for such longer period as may be required by the Administrator.

(Approved by the Office of Management and Budget under control number 0579–0013)

Done in Washington, DC, this 28th day of February 1995.

Terry L. Medley,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 95–5406 Filed 3–3–95; 8:45 am]

BILLING CODE 3410–34–M

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9 CFR Parts 102 and 114

[Docket No. 93–136–1]

Viruses, Serums, Toxins, and Analogous Products; State-Federal Licensure of Veterinary Biologics

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the regulations concerning State-Federal licensing of veterinary biological products. The effect of the amendment would be that a Federally licensed establishment would not be allowed to produce the same veterinary biological product under both a State and Federal product license. Autogenous biologics would not be subject to the same requirement, in that a Federally licensed establishment could hold both State and Federal product licenses for autogenous biologics, but must choose to produce each specific serial of such biologic

under either a State or Federal product license. No autogenous biologic could be produced at the same time under both a Federal and State license. The amendment is necessary in order to ensure the integrity of the Federal licensing system and the safety of biological products produced in Federally licensed establishments.

We are also removing outdated sections from the regulations referring to interim establishment licenses and exemption procedures that were permitted during the 5-year transition period to attain Federal licensure under the 1985 amendments to the Virus-Serum-Toxin Act.

DATES: Consideration will be given only to comments received on or before May 5, 1995.

ADDRESSES: Please send an original and three copies of your comments to Docket No. 93–136–1, Animal and Plant Health Inspection service, Regulatory Analysis and Development, Program and Policy Development, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comments refer to Docket No. 93–136–1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect comments are requests to call ahead on (202) 690–2817 to facilitate entry into the comment reading room.

FOR FURTHER INFORMATION CONTACT: Dr. David A. Espeseth, Deputy Director, Veterinary Biologics, BBEP, APHIS, USDA, 4700 River Road Unit 148, Riverdale, MD 20723–1237, (301) 734–8245.

SUPPLEMENTARY INFORMATION:

Background

The Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture, licenses veterinary biological products under the Virus-Serum-Toxin Act (21 U.S.C. 151–159, hereinafter, the Act), as amended by the Food Security Act of 1985. Veterinary biologics licensed by APHIS include products such as vaccines, antitoxins, viruses, diagnostics, and autogenous biologics (vaccines, bacterins, and toxoids) which are normally used in the herd of origin (the herd from which the disease causing microorganism is derived) to immunize animals against infectious disease.

Under the Act, veterinary biological products are licensed on the basis of their purity, safety, potency, and efficacy. The 1985 amendments to the Act exempt certain products from the requirement that they be produced pursuant to an unsuspended and unrevoked Federal license. Such products include those which are prepared solely for distribution within the State of production pursuant to a license granted by such State under a program approved by the Administrator of APHIS.

The regulations in 9 CFR part 102 contain Federal licensing provisions for biological products. This proposed rule would amend the regulations in part 102 by removing the outdated reference to Federal interim licenses in § 102.1 and by removing § 102.4(h), which refers to outdated provisions. We would also be making minor editorial changes to § 102.4(b)(3) and § 102.6 (introductory paragraph and paragraph (a)) to reflect organizational changes within APHIS.

The regulations in 9 CFR part 114 prescribe conditions under which an unlicensed product may be prepared in a USDA-licensed establishment. Section 114.2(c) prohibits the production of unlicensed veterinary biological products in licensed establishments, except when an establishment is licensed by USDA for an interim period as provided in § 114.2(b), when production of an experimental biological product is authorized in accordance with 9 CFR part 103, or when biological products are subject to the provisions of § 107.2 (products produced under State license).

The proposed rule would amend part 114 by removing from § 114.2 paragraphs (b) and (d) which refer to outdated provisions for interim licenses and to certain exemption procedures that were used in implementing the 5-year transition to Federal licensure under the 1985 amendments to the Virus-Serum-Toxin Act.

The proposed rule would also establish the conditions that must be maintained when a State-licensed veterinary biological product is produced in an establishment holding a U.S. Veterinary Biologics Establishment License. The proposed rule would require that an establishment holding a U.S. Veterinary Biologics Establishment License that is also producing products licensed by a State may produce a product either under a U.S. Veterinary Biological Product License or a State product license, but the establishment cannot produce the same product under both USDA and State product licenses. It should be noted that in order to be Federally licensed, an establishment must hold at least one Federal product license. Autogenous biologics would not be subject to the proposed requirement in that an establishment may hold both a State and Federal product license for autogenous biologics but each serial of an autogenous biologic must either be produced pursuant to the State license or the Federal license. The wide variety of different autogenous biologics that are made and the different conditions for their use dictate the need for choosing to produce some of these products under a State product license and others under a USDA product license. This choice would permit such establishments to produce autogenous biologics for intrastate use only, under a State product license, or for both intrastate or interstate use, under a U.S. Veterinary Biological Product License, provided that certain conditions of production are maintained. This proposed rule would define such conditions and ensure that the primary regulatory responsibility for each serial of product is clearly identified prior to production.

Under the proposed amendments, a biological product produced in a USDA-licensed establishment could be produced under either a State or U.S. Veterinary Biological Product License, but not both. Prior to the issuance of a U.S. Veterinary Biological Product License (including a conditional license), any State product license for the same product would have to be surrendered to the State licensing authority. As explained previously, autogenous biologics would not be subject to these requirements.

Under the proposed amendments, State-licensed products (including autogenous biologics) would only be allowed to be distributed or shipped intrastate, would not be allowed to bear a U.S. Veterinary Biological Product License Number, or otherwise be represented as having met the requirements for USDA product licensure. Labeling of State- and USDA-licensed products produced in the same establishment would be required to be distinctly different in color and design.

All biological products in USDA-licensed establishments, whether State- or USDA-licensed, would only be prepared in locations indicated in legends filed in accordance with 9 CFR part 108. A description of each State-licensed product would have to be filed with APHIS as part of the blueprint legends that is sufficient for APHIS to determine any risk to other products in the establishment and to ensure that contamination does not occur during production.

The proposed amendments would also specify that certain reporting and recordkeeping requirements have to be met for both State- and USDA-licensed products.

The proposed amendments under § 114.2(c) would require that autogenous biological products produced in a USDA-licensed establishment be identified as produced under the provisions of the State license or the Federal license at the time that a culture of microorganisms (the isolate) is received at the establishment. If, after producing the product pursuant to one license, the licensee elects to produce an autogenous biologic from the same isolate under the other license, approval of the other licensing authority would have to be obtained.

In addition, the proposed amendment would require that a State-licensed autogenous biologic prepared in a Federally licensed establishment bear a ''true name'' indicating the State of licensure, such as ''(name of State) Autogenous Bacterin'' or ''(name of State) Autogenous Vaccine.''

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for purposes of Executive Order 12866, and, therefore, has not been reviewed by the Office of Management and Budget.

The effect of the proposed rule would be to remove outdated sections from the regulations in §§ 102.1 and 102.4(h) and § 114.2 (b) and (d). These sections refer to outdated provisions related to the implementation of the 1985 amendments to the Virus-Serum-Toxin Act. These provisions expired on June 30, 1991.

The proposed rule would also establish conditions applicable to some 100 producers to prepare a biological product under either a State or USDA product license in a USDA licensed establishment. An exception would be provided for autogenous biologics. The proposed amendment would not have an adverse economic impact on these producers of biologics since it would still allow the production of both State and Federally licensed products in Federally licensed establishments. Therefore, it is not anticipated that the amendment would impose economic burdens on producers or small businesses.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12778

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are in conflict with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This document contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

List of Subjects

9 CFR Part 102

Animal biologics, Reporting and recordkeeping requirements.

9 CFR Part 114

Animal biologics, Reporting and recordkeeping requirements.

Accordingly, 9 CFR parts 102 and 114 would be amended as follows:

PART 102—LICENSES FOR BIOLOGICAL PRODUCTS

1. The authority citation for part 102 would continue to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.17, 2.51, and 371.2(d).

§ 102.1 [Revised]

2. Section 102.1 would be revised to read as follows:

Each establishment qualified to prepare biological products under the Virus-Serum-Toxin Act shall hold an unexpired and unrevoked U.S. Veterinary Biologics Establishment License issued by the Administrator and a U.S. Veterinary Biological Product License for each product prepared in such establishment unless the product is subject to the provisions of 9 CFR parts 103 or 106 of this subchapter.

§ 102.4 [Amended]

3. In § 102.4, paragraph (b)(3), the words ''Veterinary Services'' are removed and the words ''Animal and Plant Health Inspection Service'' are added in their place.

4. In § 102.4, paragraph (h) would be removed.

§ 102.6 [Amended]

5. In § 102.6, in the introductory paragraph and paragraph (a), the term ''Deputy'' is removed.

PART 114—PRODUCTION REQUIREMENTS FOR BIOLOGICAL PRODUCTS

6. The authority citation for part 114 would be revised to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.17, 2.51, and 371.2(d).

7. Section 114.2, paragraphs (b) and (d) would be removed; paragraph (c) would be redesignated paragraph (b) and revised; and a new paragraph (c) would be added to read as follows:

§ 114.2 Products not prepared under license.

* * * * *

(b) Except as provided in 9 CFR part 103, a biological product shall not be prepared in a licensed establishment unless the person to whom the establishment license is issued holds an unexpired, unsuspended, and unrevoked product license issued by the Administrator to prepare such biological product, or unless the products prepared are subject to the provisions of § 107.2 of this subchapter.

(c) A biological product produced in a USDA-licensed establishment shall be produced under a U.S. Veterinary Biological Product License or a License granted by a State under § 107.2 (referred to as a State biological product license and the products prepared pursuant thereto as State-licensed biological products, including autogenous biologics), but not under both a U.S. Veterinary Biological Product License and a State biological product license. Before a U.S. Veterinary Biological Product License (including a conditional license) is issued, the licensee shall relinquish its State license for that product: *Provided*, That autogenous biologics shall not be subject to this provision when they are prepared in accordance with the provisions of paragraph (c)(5) of this section.

(1) State-licensed biological products (including autogenous biologics) shall only be distributed or shipped intrastate, must not bear a U.S. Veterinary Biologics Establishment License Number, and must not otherwise be represented in any manner as having met the requirements for a U.S. Veterinary Biological Product license. Labeling of State- and USDA-licensed biological products produced in the same establishment must be distinctly different in color and design.

(2) All biological products in USDA-licensed establishments, whether licensed by USDA or by the State, shall be prepared only in locations indicated in legends filed in accordance with 9 CFR part 108. A description of each State-licensed product must be filed with the Animal and Plant Health Inspection Service as part of the blueprint legends and must be sufficient for Animal and Plant Health Inspection Service to determine any risk to the production of other products in the licensed establishment and to determine that adequate procedures are followed to prevent contamination during production.

(3) Records in such establishments must be maintained in accordance with §§ 116.1 and 116.2 of this subchapter and shall include all products licensed by the State or USDA.

(4) Reports prescribed in § 116.5 of this subchapter for USDA-licensed establishments shall be submitted for all veterinary biological products in the establishment.

(5) Under the following conditions, an autogenous biologic may be produced in a USDA-licensed establishment under either a State or U.S. Veterinary Biological Product License:

(i) When a culture of microorganisms, isolated from a herd in a State, is received at a USDA-licensed establishment that is in the same State but that holds both a State and a U.S. Veterinary Biological Products License for autogenous biologics, the isolate shall be designated by the licensee for use in the production of an autogenous biological product under either the State product license, or the U.S. Veterinary Biological Product License: *Provided*, That the isolate meets the requirements of the respective regulatory authority for an autogenous biologic. If, after producing the product pursuant to one license, the licensee elects to produce an autogenous biologic from the same isolate under provisions of the other license, the licensee may do so only with the approval of the other licensing authority.

(ii) The true name of a State-licensed autogenous biologic shall specify the State of licensure: e.g. ''(State) Autogenous Bacterin'' or ''(State) Autogenous Vaccine''.

Done in Washington, DC, this 28th day of February 1995.

Terry L. Medley,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 95–5407 Filed 3–3–95; 8:45 am]

BILLING CODE 3410–34–M

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

Requirements for the Special Packaging of Household Substances; Opportunity for Oral Comment

AGENCY: Consumer Product Safety Commission.

ACTION: Opportunity for presentation of oral public comments.

SUMMARY: The Commission announces an opportunity for the presentation of oral comments on two issues that were recently raised concerning amendments the Commission is considering to its regulations under the Poison Prevention Packaging Act of 1970 (PPPA) for child-resistant packaging to change the child and adult tests under which child-resistant packaging is evaluated.

Immediately after issuing a rule amending the PPPA test protocol, the Commission was provided with comments on the final rule that had not previously been submitted to the agency during the course of the rulemaking. As a result, the Commission, on February 9, 1995, voted to withhold publication of the final rule in order to consider these new arguments.

The new arguments can be summarized as follows. First, in establishing an adult test panel consisting of adults aged 60–75, the Commission allegedly exceeded its statutory authority to require that child-resistant packaging not be difficult for ''normal adults'' to use properly. Second, the rule allegedly addresses consumer convenience, rather than safety, which the comment claims is not properly the subject of a Commission regulation.

The Commission has provided that written comments, limited to these two issues, may be submitted until March 7, 1995. In addition, the Commission is providing the opportunity for interested parties to present oral comments, on these two issues alone, limited to a maximum of 10 minutes per commenter.

DATES: Oral comments limited to the new issues described below may be presented to the Commission at a Commission hearing beginning at 10:00 a.m., March 16, 1995. A request to present oral comments and an outline or text of the comments must be received by the Commission on or before March 10, 1995.

ADDRESSES: The hearing will be held in the Commission's Hearing Room, 4330 East-West Highway, 4th Floor, Bethesda, MD 20814. Requests to present comments and outlines or text of the comments should be mailed to the Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207, or delivered to the Office of the Secretary, Consumer Product Safety Commission, Room 501, 4340 East-West Highway, Bethesda, MD 20814.

FOR FURTHER INFORMATION CONTACT: Suzanne Barone, Ph.D., Project Manager, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504–0477, ext. 1196.

SUPPLEMENTARY INFORMATION: The Poison Prevention Packaging Act of 1970 (''PPPA''), 15 U.S.C. 1471–1476, authorizes the Consumer Product Safety Commission to issue requirements that certain household substances be sold in child-resistant (''CR'') packaging. Under the PPPA, the Commission has defined and established standards for such ''special'' packaging. 16 CFR 1700.1(b)(4), 1700.3, 1700.15, and 1700.20. The Commission has also determined which household substances are required to have the special packaging. 16 CFR 1700.14.

Congress provided that to comply with the special packaging requirements, a package must resist entry by most young children and must be ''not difficult'' for ''normal adults'' to open and properly resecure, within specified time periods. 15 U.S.C. 1471(4). The Commission's existing regulations were developed before the widespread use of CR packaging (''CRP'') and, therefore, without the benefit of the actual use experience and test data that since have become available.

The current adult test protocol, 16 CFR 1700.20(a) (4) and (5), specifies a test panel of 100 adults, ages 18 through 45 years. Seventy percent of the adults must be females and 30 percent must be males. The test period is 5 minutes. The adults are given the test package and asked to open and then properly close the package. For a package to meet the PPPA effectiveness criteria, at least 90 percent of the adults must be able to open and, if appropriate, properly close the package within the 5-minute test period. 16 CFR 1700.15(b)(2).

Although the PPPA has significantly reduced the number of poisonings of young children, deaths and injuries resulting from these accidental ingestions continue to be a substantial problem. For example, in 1993 alone, approximately 140,000 children under 5 years old were treated in hospital emergency rooms for suspected or actual poisonings. Also in 1993, poison control centers received reports of more